IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF MISSISSIPPI
OXFORD DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. DELTA PHARMA, INC., a corporation, and TOMMY T. SIMPSON and CHARLES MICHAEL HARRISON, individuals, Defendants.	)	Civil Action No. 3:18cv127-NBB-JMV **COMPLAINT FOR PERMANENT INJUNCTION**

The United States of America, Plaintiff, by and through its undersigned counsel, and on behalf of the United States Food and Drug Administration ("FDA"), respectfully represents as follows:

1. This statutory injunction proceeding is brought under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 332(a), and this Court's inherent equitable authority, to permanently enjoin the defendants, Delta Pharma, Inc. ("Delta Pharma"), a corporation, and Tommy T. Simpson and Charles Michael Harrison, individuals (collectively, "Defendants") from: (a) violating 21 U.S.C. § 331(a) by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) and 351(a)(2)(B), and that are misbranded within the meaning of 21 U.S.C. § 352(f)(1); (b) violating 21 U.S.C. § 331(k) by causing articles of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) and 351(a)(2)(B), and to become misbranded within the meaning of 21 U.S.C. § 352(f)(1), while such drugs are held for sale after shipment of one or more of their components in interstate commerce;

and (c) violating 21 U.S.C. § 331(d) by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, new drugs, as defined by 21 U.S.C. § 321(p), that are neither approved under 21 U.S.C. § 355, nor exempt from approval.

Jurisdiction and Venue

2. This Court has jurisdiction over the subject matter and all parties to this action under 28 U.S.C. §§ 1331, 1337, and 1345 and 21 U.S.C. § 332(a).

3. Venue in this district is proper under 28 U.S.C. § 1391(b) and (c).

Defendants and Their Operations

4. Delta Pharma is a Mississippi corporation currently located at 114 W. Mulberry Street, Ripley, Mississippi, within the jurisdiction of this Court. Delta Pharma has been manufacturing drug products since April 2001 and holds active Sterile Product Outsourcer Facility and Wholesaler Permits in Mississippi. Delta Pharma registered as an outsourcing facility pursuant to 21 U.S.C. § 353b on August 6, 2014, and it most recently re-registered as an outsourcing facility on October 20, 2017.

5. Tommy T. Simpson is Delta Pharma's President and seventy-five percent owner. Defendant Simpson is the person most responsible for Delta Pharma's operations, including, but not limited to, manufacturing and quality operations, and he has the authority to prevent, detect, and correct violations. Defendant Simpson performs his duties at Delta Pharma, within the jurisdiction of this Court.

6. Charles Michael Harrison is Delta Pharma's Vice President and Pharmacist in Charge. Defendant Harrison also participates in manufacturing and quality operations. In Defendant Simpson's absence, Defendant Harrison is the person most responsible for Delta

Pharma's manufacturing operations, and has the authority to prevent, detect, and correct violations. Defendant Harrison performs his duties at Delta Pharma, within the jurisdiction of this Court.

7. During their regular course of business, Defendants manufacture, process, pack, label, hold, and distribute articles of drug, within the meaning of 21 U.S.C. § 321(g)(1), including sterile injectable drugs. Sterile drugs include drugs that are required to be sterile under Federal or state law or drugs that, by nature of their intended use or method of administration, are expected to be sterile ("sterile drugs"). *See* 21 U.S.C. § 353b(d)(5). Defendants' sterile drugs include injectable corticosteroids and antihistamines, such as Dexamethasone Acetate Suspension, Betasone SA-6, Delta MP-100, Betasone, and Bromphed.

8. Defendants do not distribute to individual patients with prescriptions, but instead fill orders for compounded drugs for "office use" (also referred to as "office stock") to doctors' offices in multiple states.

9. Defendants manufacture drugs at Delta Pharma using components that were shipped in interstate commerce, including components from New York and New Jersey.

10. During their regular course of business, Defendants distributed their drug Delta MP-100 with labels that omitted required storage and handling instructions. Defendants also distributed their drug Dexamethasone Acetate Suspension, which is not distributed pursuant to patient-specific prescriptions, with labels that omitted the required statement "Office Use Only".

The Act's Requirements

11. Under the Act, a "drug" includes any article that is "intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," 21 U.S.C. § 321(g)(1)(B), and that is "intended to affect the structure or any function of the body." 21 U.S.C. § 321(g)(1)(C).

12. A drug is deemed to be adulterated "if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health." 21 U.S.C. § 351(a)(2)(A).

13. The Act requires that drugs be manufactured in accordance with current good manufacturing practice ("CGMP"). 21 U.S.C. § 351(a)(2)(B); *see also* 21 C.F.R. § 210.1(b). A drug is deemed to be adulterated if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with CGMP to assure that it meets the requirements of the Act as to safety and that it has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess, regardless of whether the drug is actually defective in some way. FDA has promulgated CGMP regulations for drugs at 21 C.F.R. Parts 210 and 211.

14. A drug is deemed to be misbranded "unless its labeling bears adequate directions for use." 21 U.S.C. § 352(f)(1).

15. The Act requires, subject to certain exceptions not applicable here, that drug manufacturers obtain FDA approval of a new drug application ("NDA"), an abbreviated new drug application ("ANDA"), or an investigational new drug exception ("IND") with respect to any new drug that manufacturers introduce into interstate commerce. 21 U.S.C. §§ 331(d), 355(a). A "new drug" includes any drug "the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 321(p)(1).

16. The label of a drug compounded in an outsourcing facility must contain several specified statements and information, including storage and handling instructions, 21 U.S.C.

§ 353b(a)(10)(A)(iii)(VII), and the statement "Office Use Only" if the drug is not dispensed or distributed pursuant to a patient-specific prescription, 21 U.S.C. § 353b(a)(10)(A)(iii)(IX), to be eligible for the exemptions applicable to outsourcing facilities.

The Act's Exemptions for Compounded Drugs

17. Compounding generally refers to the practice in which a licensed pharmacist or physician (or, in the case of an "outsourcing facility," a person under the direct supervision of a licensed pharmacist) combines, mixes, or alters ingredients to create a drug. Outsourcing facilities are not required to obtain prescriptions for identified individual patients. *See* 21 U.S.C. § 353b(d)(4)(C).

18. Under the Act, an "outsourcing facility" is a facility that engages in the compounding of sterile drugs, registers as an outsourcing facility pursuant to 21 U.S.C. § 353b(b), and complies with all of the requirements of 21 U.S.C. § 353b. *See* 21 U.S.C. § 353b(d)(4)(A).

19. Under the Act, drug products compounded in a registered outsourcing facility are exempt from adequate directions for use and premarket approval requirements if the drugs compounded by the outsourcing facility are compounded in accordance with all of the conditions in 21 U.S.C. § 353b. *See* 21 U.S.C. § 353b(a).

20. Outsourcing facilities under 21 U.S.C. § 353b are not exempt from complying with CGMP. *See* 21 U.S.C. § 353b(a).

FDA's February 2017 Inspection

21. FDA conducted its most recent inspection of Delta Pharma between February 13 and 23, 2017 ("2017 Inspection").

22. FDA investigators observed and documented numerous insanitary conditions, as described further in paragraph 25 below, and deviations from CGMP requirements for drugs, as described further in paragraph 28 below.

23. As discussed further in paragraphs 33 and 38 below, FDA also observed and documented that Defendants manufactured and introduced into interstate commerce drugs with labels that omitted information required by 21 U.S.C. § 353b(a)(10), and this inspection also revealed that Defendants manufacture and introduce into interstate commerce unapproved new drugs and misbranded drugs.

24. At the close of the 2017 Inspection, FDA investigators issued a Form FDA-483, List of Inspectional Observations ("FDA-483") to Defendant Simpson and discussed the FDA-483 observations with him and Defendant Harrison, among others.

Adulteration Due to Insanitary Conditions

25. The insanitary conditions observed by FDA at the Delta Pharma facility during FDA's 2017 Inspection establish that drugs manufactured and distributed by Defendants are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A). The insanitary conditions observed by FDA during the 2017 Inspection include, but are not limited to:

a. Use of fifty-foot-long tubing to process purportedly sterile drugs, without determining whether Defendants' procedures for sterilizing the tubing are effective or assessing its compatibility with Defendants' drug products to ensure that chemicals or particulates from the tubing do not leach, interact, or otherwise contaminate Defendants' drug products;

b. Failure to adequately conduct process simulation studies (media fills) to provide assurance that Defendants' aseptic processes are effective; and

c. Failure to appropriately use a sporicidal agent to disinfect areas where Defendants process their purportedly sterile injectable drug products.

26. Defendants violate 21 U.S.C. § 331(a) by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A), in that they are prepared, packed, or held under insanitary conditions whereby they may have been contaminated with filth or rendered injurious to health.

27. Defendants violate 21 U.S.C. § 331(k) by causing articles of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A), while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

Adulteration Due to CGMP Violations

28. During the 2017 Inspection, FDA investigators documented numerous deviations from CGMP requirements for drugs, including but not limited to Defendants' failure to:

a. Establish and follow appropriate written procedures that are designed to prevent microbiological contamination of drug products purporting to be sterile, including validation of all aseptic and sterilization processes, *see* 21 C.F.R. § 211.113(b);

b. Ensure and validate that drug product containers and closures are adequately sterilized and processed to remove pyrogenic properties (depyrogenation), *see* 21 C.F.R. § 211.94(c);

c. Establish adequate control systems necessary to prevent contamination during aseptic processing, including, but not limited to, adequate environmental monitoring, and an adequate system for cleaning and disinfecting the room and equipment to produce aseptic conditions, *see* 21 C.F.R. § 211.42(c)(10)(iv)(v);

d. Establish adequate written testing program to assess stability characteristics of Defendants' drug products, *see* 21 C.F.R. § 211.166(a);

e. Thoroughly review and investigate any unexplained discrepancy or the failure of a batch or any of its components to meet any of its specifications, *see* 21 C.F.R. § 211.192; and

f. Establish an adequate quality control unit that has the responsibility and authority to approve or reject all components, drug product containers, closures, in-process materials, packaging material, labeling, and drug products, and has the authority to investigate any errors that may have occurred, *see* 21 C.F.R. § 211.22(a).

29. These observations establish that Defendants' drugs were adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B).

30. Defendants violate 21 U.S.C. § 331(a) by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug that are adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), in that the methods used in, or the facilities or controls used for, their manufacturing, processing, packing, and holding do not comply with CGMP to assure that they meet the requirements of the Act as to their safety and that they have the identity and strength, and meet the quality and purity characteristics, which they purport or are represented to possess.

31. Defendants also violate 21 U.S.C. § 331(k) by causing articles of drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(B), while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

Unapproved New Drugs

32. Two of Defendants' compounded drugs, Delta MP-100 and Dexamethasone Acetate Suspension, are not generally recognized as safe and effective because there are no published adequate and well-controlled clinical studies of those drugs upon which qualified experts could conclude that the drugs are safe and effective. Therefore, they are new drugs within the meaning of 21 U.S.C. § 321(p).

33. Drugs manufactured at an outsourcing facility in compliance with 21 U.S.C. § 353b are exempt from the new drug approval requirements under 21 U.S.C. § 355. 21 U.S.C. § 353b(a). To be entitled to that exemption, Defendants need to meet all of the statutory elements of 21 U.S.C. § 353b for each drug product. *See* 21 U.S.C. § 353b(a). At the time of the 2017 Inspection, the labels for many of Defendants' drugs, including but not limited to Delta MP-100 and Dexamethasone Acetate Suspension, failed to include the statement "Not for Resale" as required by 21 U.S.C. § 353b(a)(10)(A)(iii)(IX). Defendants have corrected this labeling deficiency; however, the labels for these two drugs fail to include other required information. Specifically, the labels for Defendants' Delta MP-100 does not include the required storage and handling instructions and the labels of Defendants' Dexamethasone Acetate Suspension, which is not distributed pursuant to patient-specific prescriptions, does not include the required statement "Office Use Only." 21 U.S.C. § 353b(a)(10)(A)(iii)(VII) and 353b(a)(10)(A)(iii)(IX). Thus, these drug products, which are new drugs, are not exempt from the approval requirements. *See* 21 U.S.C. § 353b(a) and 353b(d)(4)(A).

34. Defendants' drugs, Delta MP-100 and Dexamethasone Acetate Suspension, lack an approved NDA or ANDA, as required by 21 U.S.C. § 355, and are not otherwise exempt from approval under 21 U.S.C. § 355(i). Hence, these drug products are unapproved new drugs.

35. Defendants' distribution into interstate commerce of these unapproved new drugs violates 21 U.S.C. § 331(d).

Misbranding Due to Inadequate Directions for Use

36. Due to their toxicity or other potentiality for harmful effect, or the method of their use, or the collateral measures necessary to their use, Defendants' drugs are not safe for use except under the supervision of a practitioner licensed by law to administer such drugs. As such, Defendants' drugs are "prescription drugs" within the meaning of 21 U.S.C. § 353(b)(1)(A).

37. "Adequate directions for use" means directions under which a layperson could use a drug safely and effectively for the purposes for which the drug is intended. 21 C.F.R. § 201.5. A prescription drug, by definition, cannot bear adequate directions for use by a layperson because such drug must be administered under the supervision of a licensed practitioner. *See* 21 U.S.C. § 353(b)(1). FDA has established exemptions for certain drug products from the requirements that labeling bear adequate directions for use, but because Defendants' drug products are unapproved new drugs, they do not satisfy the conditions for any of these exemptions. *See* 21 C.F.R. §§ 201.115, 201.100.

38. Because Delta Pharma was registered with FDA as an outsourcing facility at the time of FDA's 2017 Inspection, it was required to comply with all of the requirements of 21 U.S.C. § 353b to be able to avail itself of the exemptions in that section. Because the labels for Defendants' Delta MP-100 fail to include storage and handling instructions and the labels for Defendants' Dexamethasone Acetate Suspension, which is not distributed pursuant to patient-specific prescriptions, fail to include the statement "Office Use Only" in violation of 21 U.S.C. § 353b(a)(10)(A)(iii)(VII) and 353b(a)(10)(A)(iii)(IX), these compounded drugs do not qualify

for 21 U.S.C. § 353b's exemption from the requirement for adequate directions for use contained in 21 U.S.C. § 352(f)(1) and are thus misbranded. *See* 21 U.S.C. § 353b(a), 353b(d)(4)(A).

39. Defendants violate 21 U.S.C. § 331(a) by introducing and causing to be introduced, and delivering and causing to be delivered for introduction, into interstate commerce, articles of drug that are misbranded within the meaning of 21 U.S.C. § 352(f)(1), in that the labeling of the drugs fails to bear adequate directions for use, and the drugs are not exempt from the requirements of 21 U.S.C. § 352(f)(1).

40. Defendants violate 21 U.S.C. § 331(k) by causing articles of drug that are not exempt from the requirements of 21 U.S.C. § 352(f)(1) to become misbranded within the meaning of 21 U.S.C. § 352(f)(1), while such drugs are held for sale after shipment of one or more of their components in interstate commerce.

Prior Inspections and Warnings to Defendants

41. FDA previously inspected Delta Pharma between May 16 and 24, 2016 ("2016 Inspection") and observed similar insanitary conditions and CGMP deviations to those observed in the 2017 Inspection, including, but not limited to, failure to determine whether the tubing is compatible with Defendants' drug products; failure to establish appropriate written procedures, including validation of all aseptic and sterilization processes; failure to assure that drug product containers and closures are suitable for their intended use by cleaning, sterilizing, and processing them to remove pyrogenic properties (depyrogenation), and to validate depyrogenation processes; and failure to establish adequate control systems necessary to prevent contamination during aseptic processing, including environmental monitoring. Despite these violations, Defendants continued to manufacture drugs without taking adequate corrective actions.

42. At the close of the 2016 Inspection, FDA investigators issued a FDA-483 to Defendant Simpson and discussed the inspectional observations with him and Defendant Harrison, among others.

43. FDA Investigators also inspected Delta Pharma in October 2013, September 2010, October 2007, and March 2004. After each inspection, FDA issued a multi-item FDA-483, citing numerous observations, many of which were the same or similar to insanitary conditions and CGMP deviations observed during FDA's 2016 and 2017 Inspections, including, but not limited to: failure to establish appropriate written procedures, including validation of all aseptic and sterilization processes; failure to assure that drug product containers and closures are suitable for their intended use by cleaning, sterilizing, and processing them to remove pyrogenic properties (depyrogenation), and to validate depyrogenation processes; and failure to establish adequate control systems necessary to prevent contamination during aseptic processing, including monitoring environmental conditions.

44. FDA issued a Warning Letter dated December 9, 2014, to Defendant Simpson notifying him that Delta Pharma's drug products were (a) adulterated due to the presence of insanitary conditions and violations of CGMP, (b) unapproved new drugs, and (c) misbranded because their labeling failed to include adequate directions for use. The 2014 Warning Letter followed a September 17, 2004 Warning Letter to Defendant Simpson raising similar concerns. Both Warning Letters noted that the failure to take prompt action to correct deficiencies could result in legal action without further notice, including seizure or injunction.

45. Despite repeated promises to correct their deficiencies, Defendants' violations persisted, as evidenced by the violations observed during the 2017 Inspection.

46. The United States believes that, unless restrained by the Court, Defendants will further violate 21 U.S.C. § 331(a), (k), and (d), in the manner alleged herein.

WHEREFORE, the United States of America respectfully requests that this Court:

I. Permanently restrain and enjoin Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from manufacturing, processing, packing, labeling, holding, or distributing any article of drug, unless and until Defendants bring their manufacturing, processing, packing, labeling, holding, and distribution operations into compliance with the Act and its implementing regulations to the satisfaction of FDA;

II. Permanently restrain and enjoin under 21 U.S.C. § 332(a) Defendants and each and all of their directors, officers, agents, representatives, employees, attorneys, successors, and assigns, and any and all persons in active concert or participation with any of them, from directly or indirectly doing or causing the following acts:

A. Violating 21 U.S.C. § 331(a) by introducing and/or causing to be introduced, and/or delivering or causing to be delivered for introduction, into interstate commerce, any drug that is adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) and/or 351(a)(2)(B), and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1);

B. Violating 21 U.S.C. § 331(k) by causing any drug to become adulterated within the meaning of 21 U.S.C. § 351(a)(2)(A) and/or 351(a)(2)(B), and/or misbranded within the meaning of 21 U.S.C. § 352(f)(1), while such drug is

held for sale after shipment of one or more of its components in interstate commerce;

C. Violating 21 U.S.C. § 331(d) by introducing and/or causing the introduction into interstate commerce, and/or delivering and/or causing the delivery for introduction into interstate commerce, of any new drug that is neither approved under 21 U.S.C. § 355, nor exempt from approval;

III. Authorize FDA pursuant to this injunction to inspect Defendants' places of business and all records relating to the receipt, manufacture, processing, packing, labeling, holding, and distribution of any drug to ensure continuing compliance with the terms of the injunction, with the costs of such inspections, including testing and sampling, to be borne by Defendants at the rates prevailing at the time the inspections are accomplished; and

IV. Award the United States costs and other such relief as the Court deems just and proper.

DATED this 4th day of June, 2018.

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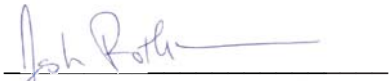

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